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Wolfgang Lechner

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LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,793	Applicant(s) LECHNER, WOLFGANG	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-15, 17, 18 and 22-25 is/are rejected.
- 7) ☒ Claim(s) 4, 16 and 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed 17 December 2007. Claims 1-25 are now pending. The Examiner acknowledges the addition of claim 25.

Claim Objections

2. The claims include reference characters which are enclosed within parentheses. The use of reference characters is considered as having no effect on the scope of the claims. Since the reference characters are not afforded patentable weight, the reference characters enclosed within parentheses apparently should be deleted from the claims. Correction is requested.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5-7, 9-12, 14-15, 17-18 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Baro et al. (U.S. Patent No. 4,399,809). Baro et al. discloses an apparatus to be applied to a stoma within the body, comprised of chambers to be inflated or deflated with a fluid in response to pressure monitored by a

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sensor. Regarding claims 1 and 3, Baro teaches a gastric band **1** having a non-extensible back such that it cannot expand outward upon inflation of the chambers (col. 4, lines 54-57). The band is arranged in such a way as to encircle the intestine near the stoma (col. 4, lines 9-13). The band may have two chambers **8**, **9** that communicate with each other via a passage **3** for the introduction and removal of fluid used to inflate and deflate the chambers such that the restriction of the stoma is controlled (col. 4, lines 27-33). The chambers are located beside each other whereby the first chamber may be located aborally (see Fig. 4).

With reference to the improvements of claim 2 and claim 5, a second chamber **9** is interpreted as a “sensor” for the detection of pressure since it responds by deflation upon a pressure increase from the stomach in relation to the consumption of food. The first chamber **8** is connected to the second chamber **9** via a passage **3** leading to a conduit **4** which is connected to a pump having a “reservoir” that supports fluid which is supplied to or removed from the chambers to ensure control of restriction (col. 3, lines 49-58 and Fig. 4). Furthermore, the first and second chambers are arranged one above the other with respect to the stomach (see Figs. 1 and 4). Referring to claim 6, a “layer” is provided between the chambers **8** and **9** as evident in Fig 4.

With reference to claims 7 and 9, a mechanical, manually activated pump is provided for pumping a fluid into the chambers. Since a passage **3** exists between the chambers, it is thus capable of distributing fluid from the second chamber into the first chamber and vice versa (col. 3, lines 49-58 and Fig. 4). Regarding claim 15, when a given pressure has been detected by sensing device **12**, decompression of the band is

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advised by removal of fluid from the first chamber of the band via the pump. Prior to eating and an increase in pressure, the band is in an inflated state, which is a result of supplying fluid from a “reservoir” of a pump to the first chamber. While fluid is supplied to both chambers, the language of claim 15 only requires supplying liquid to or removing liquid from the first chamber.

Regarding claims 10-12 and 14, Baro further provides a detection device **12**, that senses when a given pressure has been reached in the intestine, such a pressure prevailing from eating and subsequently swallowing a particular amount.

Referring to claims 17 and 18, a conduit **4** is interpreted as an air chamber arranged between a reservoir supplying fluid through the pump and the first chamber **8** (see Fig. 4). A pump is provided between the first chamber **8** and a reservoir that supplies fluid to the band.

In view of claims 23 and 24, a “further liquid-filled chamber” is provided in the band, interpreted to be a chamber which is connected to a conduit or port **20** and extends to a pump for introduction and removal of fluid from the chambers (col. 3, lines 49-58 and Figs. 1 and 7).

5. Claim 25 is rejected under 35 U.S.C. 102(e) as being anticipated by Meah (U.S. Patent No. 6,432,040). Meah discloses an implantable esophageal sphincter apparatus with an adjustable band. Regarding claim 25, Meah teaches a gastric band including a back **62** and a chamber **28** on one side of the back for arrangement on a stoma side and adjusting restriction of the stoma (col. 4, lines 50-60 and Fig. 3) comprising: a sensor **88** for detecting pressure increase in the esophagus and a control **82** for

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adjusting the restriction as a function of the detected pressure increase. In response to detected changes, a pump **74** may increase or decrease the central opening **60** (col. 5, lines 44-60).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baro et al. (U.S. Patent No. 4,399,809) in view of Imran et al. (U.S. Patent No. 7,037,343). Baro discloses the invention as claimed, see rejection supra; however Baro fails to teach a pump that is electrically driven. Imran teaches an implantable stomach prosthesis, composed of expandable members, for controlling passage of food from the stomach to the small intestine. With respect to claim 8, Imran discloses a DC powered pump for selectively inflating and deflating expandable members (col. 6, lines 40-50), or the equivalent of inflatable chambers as taught by Baro, from a reservoir. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have utilized an electric pump as suggested by Imran to introduce fluids to, and also remove them from, an inflatable chamber similar to that of Baro, acting to constrict a body lumen.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baro et al. (U.S. Patent No. 4,399,809) in view of Forsell (U.S. Pub. No. 2001/0011543). Baro discloses the invention as claimed, see rejection supra; however Baro fails to teach a pressure sensor provided in a chamber of an adjustable band. Forsell discloses an adjustable restriction member for modifying the opening of a stomach in treating obesity. Regarding claim 13, Forsell teaches a pressure sensor **23** mounted inside a restriction member **12** to detect pressure prevailing in the gastric wall of a patient [0061]. Sensor **23** detects and communicates such a pressure to a control unit **22** via electrical connections that cause a pump to introduce or remove fluid into a cavity and thus expand or decrease the restriction member [0064]. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have provided in an inflatable member of a restriction device as taught by Forsell, with a sensor for detecting pressure in a restriction band as disclosed by Baro, for communicating an accurate pressure exerted on the wall of the stomach as a result of food intake.

9. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baro et al. (U.S. Patent No. 4,399,809) in view of Chen et al. (U.S. Patent No. 5,690,691). Baro discloses the invention as claimed, see rejection supra; however Baro fails to teach a device emitting an electrical pulse for stimulating the stomach. Regarding claim 22, Chen discloses the use of electrodes for controlling the peristaltic wave and therefore stimulating the flow of food through the stomach (col. 3, lines 34-45 and col. 6, lines 43-67-col. 7, lines 1-4). Therefore, at the time of the invention it would have been obvious

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to one having ordinary skill in the art to have incorporated electrodes as suggested by Chen to a chamber sensing pressure of the stomach as taught by Baro such that electrical pulses emitted by the electrodes act to stimulate the stomach during food intake by invoking satiety and stimulating the muscles of the stomach to constrict and further decrease the stoma opening.

Allowable Subject Matter

10. Claims 4, 16 and 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: regarding claim 4, while the prior art of record teaches a second chamber, it fails to fairly teach or suggest dividing one of the chambers which will serve to introduce a fluid into an adjustable band.

In view of claim 16, the prior art fails to teach or suggest connecting two chambers with an auxillary chamber for introducing fluid to a band whereby fluid flow is restricted to such chambers by a valve. The prior art of record teaches flow between such chambers, however the flow is allowed by a passage that does not restrict movement from one chamber to the other since both chambers of the prior art serve to simultaneously adjust the restriction of the opening.

Regarding claim 19, the prior art of record teaches a pump for facilitating liquid exchange from a reservoir to a chamber, however it fails to teach or suggest a common partition wall with micropores arranged between the chambers. Furthermore, regarding

claims 20 and 21, the prior art of record does not teach or suggest a backflow channel to be arranged between the chambers since the chambers of the prior art allow flow freely between the individual chambers and do not act to limit flow via a backflow channel equipped with a valve.

Response to Arguments

11. Applicant's arguments filed 17 December 2007 with respect to the rejection of claims 1-3, 5-7, 9-12, 14-15, 17-18 and 23-24 under 35 U.S.C. 102(b) citing Baro ('809) have been fully considered and are not persuasive. Applicant contends that displacing fluid to the first chamber **8** from the second chamber **9** of the invention of Baro "would press an equal amount of fluid out conduit **4** rather than have any inflation effect on first chamber **8** for ensuring its control, as claimed." However, this argument is not persuasive. The claim does not set forth any language which would indicate independent control on behalf of the second chamber over the first chamber. In fact, the claim requires "communication" between the first and second chambers in the form of liquid displacement. Furthermore, there is no structural limitation set forth in either claim 1 or claim 2 that would act to "ensure the controlling of" such displacement. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In view of the foregoing, the

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rejection of claims 1-3, 5-7, 9-12, 14-15, 17-18 and 23-24 under 35 U.S.C. 102(b) citing Baro ('809) has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735